



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2015-0029]

Export Verification Program: Microbiological Testing of Ready-To-Eat Products Destined for Canada

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the establishment of an FSIS and Agricultural Marketing Service (AMS) Export Verification (EV) Program. The program is designed to verify establishments' control of closed-faced sandwiches destined for Canada. Among other things, Canada is requiring that closed-faced sandwiches be produced under a Hazard Analysis and Critical Control Point (HACCP) plan. Under the program, the sandwiches will be produced in establishments that are under FSIS' voluntary reimbursable inspection service and that are operating under conditions that are as consistent as practical with those under which other post-lethality exposed meat and poultry products are produced under 9 CFR part 430. Closed-faced sandwiches are under jurisdiction of the Food and Drug Administration (FDA), but FDA does not require that the sandwiches be produced under a HACCP plan. It also does not verify that the requirements of 9 CFR part 430 are met.

Consequently, FSIS and AMS are establishing this voluntary program. Once the program is implemented, only establishments participating in this program will be able to export closed-faced sandwiches to Canada.

DATES: Submit comments on or before

<http://www.ams.usda.gov/services/imports-exports/rte-canada>. The program will be implemented [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on the issues described below. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 355 E Street, SW, Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street, SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2015-0029. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street, SW, Room 164-A, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

Establishments seeking to participate in this program should contact FSIS by phone at (202) 720-0082, or by email at importexport@fsis.usda.gov.

Background

In February 2013, the Canadian Food Inspection Agency (CFIA) audited the United States' food safety system for meat

and poultry products intended for export to Canada.¹ CFIA's final audit report found that HACCP plans and Listeria monocytogenes (Lm) controls for ready-to-eat (RTE) meat products were not required when establishments prepared the products under FSIS's voluntary reimbursable inspection service. CFIA notified FSIS that CFIA requires that these products be produced according to HACCP plans and Lm controls consistent with 9 CFR part 430.

Meat and poultry products prepared in official establishments are subject to mandatory inspection by FSIS under the Federal Meat Inspection Act (21 U.S.C. 601, et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451, et seq.). FSIS considers RTE meat and poultry products to be adulterated if they test positive or come into direct contact with a food-contact surface that tests positive for Lm, Salmonella, or other pathogens. FSIS uses microbiological testing in its mandatory inspection programs to verify that establishments have adequate food safety systems, including measures to control Lm (9 CFR part 430).

However, not all RTE products containing meat or poultry fall under FSIS's regulatory jurisdiction. Closed-faced

¹ *Final Report Of An Audit Conducted In The United States February 5th, through February 22nd, 2013 Evaluating The Food Safety Systems Governing The Production Of Meat And Poultry Products Intended For Export To Canada*, available at: <http://www.inspection.gc.ca/food/meat-and-poultry-products/imports/audits-of-meat-inspection-programs/final-report-of-an-audit-us-/eng/1404919271012/1404921262798?chap=8#s5c8>.

sandwiches are not considered traditional products of the meat or poultry industries, and therefore they fall under the regulatory jurisdiction of FDA.

Establishments producing these RTE products may receive FSIS reimbursable voluntary inspection, but this inspection does not include microbiological testing for pathogen control or verification of HACCP plans or sanitation standard operating procedures (Sanitation SOP). FSIS conducts this reimbursable voluntary inspection to certify products for export under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621, et seq.). The inspection is intended to meet the importing country's requirements for U.S.-produced meat and poultry products (9 CFR 350.3(b); 9 CFR 381.104-.107). Canada's requirements identified in the FSIS Export Library do not require Lm testing, HACCP, or Sanitation SOPs for RTE products. The FSIS Export Library is available at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country>.

AMS Testing Program

AMS and FSIS have developed a collaborative testing program to verify pathogen control for closed-face sandwiches produced under FSIS voluntary inspection and intended for export to

Canada. This program, which AMS will administer, may eventually include other RTE products. The program will include two types of testing, routine and intensified, to ensure that participating establishments are controlling Lm and Salmonella.

For routine testing, AMS will randomly select dates once per year when product samples will be collected. FSIS will collect the product samples and pack them for shipment to the USDA National Science Laboratories in Gastonia, North Carolina. FSIS will collect six samples regardless of plant size, production volume, or process design. If an establishment produces both post-lethality-exposed and non-post-lethality-exposed products, six product samples will be taken from the former and two from the latter. AMS will analyze the samples for Lm and Salmonella and will require that establishments hold or maintain control of the product until acceptable results become available. If the product is positive, the establishment will have to properly dispose of the affected product in accordance with FDA regulations.

At least once per year, AMS also will select dates for intensified testing at a participating establishment. AMS will also conduct this testing if it finds a positive Lm or Salmonella result or in response to continuing sanitation non-compliances at the establishment. The samples will vary in

number depending on whether product is being tested for Lm or Salmonella but will always include environmental, product, and food-contact-surface samples. AMS will collect the samples.

For both types of testing, the establishment will pay all costs for sample collection, shipping, shipping materials, and analysis. See <http://www.ams.usda.gov/services/imports-exports/rte-canada> for a full description of the program, including sample collection and laboratory testing methods.

HACCP Verification

In order for the establishments to meet Canada's requirements for import of closed-face sandwiches, FSIS will offer voluntary inspection services and will verify that the establishments are producing these products under HACCP and Sanitation SOPs. Therefore, to ship this product to Canada, establishments will need to comply with the requirements in 9 CFR part 417 and 9 CFR 416.11-.17.

By participating in the EV program and receiving voluntary inspection from FSIS (including verification of HACCP plans and Sanitation SOPs), establishments that produce closed-face sandwiches and that meet all FSIS and AMS EV program requirements will be able to meet Canada's stated import requirements for closed-faced sandwiches. To receive these services, establishments should contact FSIS at (202) 720-0082,

or by email at importexport@fsis.usda.gov.

Comments are invited on: (a) the timetable for implementation of this program, including readiness to participate in the program's pathogen testing and HACCP verification, and business and trade interests affected by compliance or non-compliance with the program; (b) how the proposed programs can be implemented operationally to avoid disruption of trade or business activities; and (c) any other operational issues that commenters need clarified. FSIS will clarify any issues or make adjustments to the implementation date of the program in a Constituent Update.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed

online at

http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all aspects of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make this publication available through the FSIS Constituent Update, which is used to provide information

regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a broad and diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:
<http://www.fsis.usda.gov/subscribe>. Subscription options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: October 28, 2015.

Alfred V. Almanza,
Acting Administrator.

BILLING CODE 3410-DM-P

